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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/803,659

03/12/2001

Derk J. Hogenkamp

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10/21/2002

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 10/21/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/803,659

Applicant(s)

HOGENKAMP ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 14, 15, 17-26, 28, 29, 31-39, 41-48 and 59-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 15, 17-26, 28, 29, 31-38, 41-48 and 61-68 is/are rejected.
- 7) ☒ Claim(s) 39, 59 and 60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other:

### DETAILED ACTION

Applicants' amendment filed on 7/12/2002 is made of record.

After entering the amendment, claims 1-12, 14-15, 17-26, 28-29, 31-39, 41-48 and 59-68 are pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 14-15, 17-26, 28-29, 31-39, 41-48 and 59-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. In claim 1-2, 17,31 and 50 recitation of the term "prodrug" is deemed as indefinite. Prodrugs in general and as noted in specification, page 20, are compounds, which undergo in vivo hydrolysis to parent active drugs. In that sense recitation of prodrug is acceptable. However, the definition of various R, groups include such groups, namely esters, amides, alkoxycarbonyl etc. and therefore it is not clear what is the difference between these variable groups and the prodrug groups.

Applicants' argument to overcome this rejection is not persuasive. Applicants seem to misunderstand this rejection. The issue is not how the prodrugs are made or where the groups are placed. The issue is what is difference between

those groups already recited in the variable definition and those recited as prodrug. Applicants have not addressed this issue and hence the rejection is proper and is maintained.

2. Claims also recite "aminocarbonyl" group and "carboxamido" group that render these claims indefinite as it is not clear what is difference. It implies more than what is positively recited in either of the group.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,50-51, and 61-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsutomu et al. GB 2,095,240.

Tsutomu et al. teaches several pyrimidine compounds, which include those claimed in the instant claims generically, for use as anti-allergic agents. See page 1, formula I and note the definition of R<sub>1</sub> includes (un)substituted aryl. Note the process for making it. Particularly note, Tsutomu et al teaches the intermediate compound of formula II which is also embraced in the instant claims. See page 2 for details of the process and pages 3-13 for compounds made.

Applicants' argument to overcome this rejection is not persuasive as "the oxo" group in the ring is a tautomer of instant hydroxyl. Hence the rejection is maintained.

Rest of the 102 rejections made in the previous office action have been rendered moot in view of applicants' amendment.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6, 8-11, 14-15, 17-19, 21-25 and 50-51 and 61-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Kafrawy et al. J. Chem. Soc. Pak. 14(1) 59-66, 1992.

El-Kafrawy et al. teaches several pyrimidine compounds for use as antimicrobial agents. See entire document especially page 63, compounds 4a through 4c, 5a and 5b.

Instant compounds require a carboxyl group at 2 or 4 position for R<sub>1</sub> and an amino at other available position for R<sub>2</sub>.

While said compound(s) doesn't anticipate the scope of instant claims, they are very closely related, being positional isomers of compounds i.e. 2-carboxyl and 6-amino of instant R<sub>1</sub> vs 2-amino and 6-carboxyl in the pyrimidine ring of the reference. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See In re Crounse, 150 USPQ 554; In re Norris 84 USPQ 458; In re Finely 81 USPQ 383 and 387; Ex parte Engelhardt, 208 USPQ 343; Ex parte Henkel, 130 USPQ 474, regarding positional isomers. Thus it would have been

obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

This rejection is same as made in the previous office action. Applicants argue that the compounds taught are dihydro compounds which is incorrect. See page 63, compounds 6a-e. Furthermore, the fact that the compounds showed variation in activity does not negate motivation as it is expected in the art. In addition, applicants have not provided any evident showing that all the instant compounds have the equal level of activity, a requirement which applicants expect from prior art compounds.

The rejection is proper and is maintained.

#### ***Allowable Subject Matter***

Claims 39 and 59-60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims would be allowed since specific species embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

References cited in the Information Disclosure Statements (paper # 14) are made of record.

#### **Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from

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8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Venkataraman Balasubramanian

10/19/2002